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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,745	08/29/2003	Charles S. Schasteen	NVI 5252.4	1765
321	7590	03/27/2007		
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			EXAMINER KANTAMNENI, SHOBHA	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		03/27/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/27/2007.

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uspatents@senniger.com

Office Action Summary	Application No. 10/652,745	Applicant(s) SCHASTEEN ET AL.	
	Examiner Shobha Kantamneni	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-112 is/are pending in the application.
- 4a) Of the above claim(s) 1-74 and 105-112 is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 75-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :01/13/05;
08/14/04;03/29/04;01/08/04;12/23/03.

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DETAILED ACTION

Claims 1-112 are pending in this application.

Election/Restrictions

Claims 1-74, 105-112 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Applicant's election with traverse of invention Group II, directed to a method of killing microbes in a subject comprising treating said subject with a composition of claim 1, claims 75-104 in reply filed on 12/12/2006 is acknowledged. The traversal is on-the grounds(s) that the search and examination of an entire application can be made without serious burden. This argument has been considered, but not found persuasive because although the search for the inventions is overlapping, the search for the invention of the 3 groups would not be coextensive because a search indicating the method is novel or unobvious would not extend to a holding that the product itself is novel or unobvious; similarly, a search indicating that the product is known or would have been obvious would not extend to a holding that the method is known or would have been obvious. Therefore, restriction for examination purposes as indicated is proper, and herein made final.

Claims 75-104 are examined herein on the merits as they read on the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75-104 are rejected under 35 U.S.C. 112, second paragraph, as being vague, and indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "an acceptable diluent, adjuvant or excipient" in claim 1 from which claims 75-104 depend is vague and indefinite, as it is not clear what compounds this recitation encompasses, the specification does not provide as to which diluents, adjuvants, and excipients are acceptable in the instant invention, and one of ordinary skill in the art could not ascertain the metes and bounds as to "an acceptable diluent, adjuvant or excipient."

Claims 75, 96, 97 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "a subject" renders these claims indefinite. The recitation "a subject" is not clearly defined in the claims or specification. One of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to what "a subject" would be, for example, that the term "subject" would be a single cell, any biological system, an animal or a human, or any non-biological system such as skin care lotions, cleaning solutions etc. Thus, one of ordinary skill in the art could not ascertain and interpret encompassed thereby.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 75-80, 82-85, 90, 92-93, 96-99, 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivey et al. (US 5,928,686, PTO-892), and as evidenced by Blake et al. (US 2,938,053, PTO-892).

Ivey et al. discloses a high moisture solid formulation which contains about 30 % to about 90 % by weight of water, and between about 10 % to about 70 % by weight of dry matter wherein the dry matter contains 15 % by weight of 2-hydroxy-4-methylthiobutanoic acid. See column 4, lines 1-20, 47-49; lines 59-67; column 14, claims 1,8; column 10, EXAMPLE 3. It is also disclosed that a high moisture having high nutrient profile is prepared by mixing soybean meal, egg white, corn starch, corn meal, Alimet, propionic acid and citric acid. See column 7, lines 1-10; column 11, TABLE 4. Feed formulations comprising Alimet, soy oil, corn starch are also fed to the birds. See column 10-column 11, Example 3, Example 4. The formulation therein is mixed with food and used to feed poultry i.e chicks, and other animal. See abstract; column 1, lines 6-14; column 3, lines 20-26. The high moisture solid may be formed by mixing the ingredients with feed, and heating the mixture by adding hot water. See column 7, lines 10-13. It is also disclosed that a group of one to four day old birds were given 20 g each of a high moisture solid consisting of gelatin and Alimet (2-hydroxy-4-(methylthio)butanoic acid) base with addition of either corn starch or corn starch and

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lysine. See column 11, Table 3. Further as evidenced by Blake et al. 2-hydroxy-4-(methylthio)butanoic acid has antimicrobial activity, antifungal activity, and is used as animal diet particularly poultry. See column 1, lines 39-41, lines 47-50, lines 58-63.

Ivey's method inherently inhibits or kills microbes in a subject such as poultry feed, since the method steps are same as the instant method steps, mixing the same compound in the same effective amount to the same subject will cause the same effect, whether or not that effect is specifically disclosed by the prior art. See *Ex parte Novitski*, 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein. Note that as evidenced by Blake et al., Alimet, 2-hydroxy-4-(methylthio)butanoic acid has antimicrobial activity, antifungal activity and thus on mixing Alimet (2-hydroxy-4-(methylthio)butanoic acid) with food inherently inhibits or kills microbes, mold in the food.

Thus, Ivey's method anticipates instant claims 75-80, 82-85, 90, 92-93, and 96-99, and 104.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75-82, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paquet et al. (CA 1261855, PTO-892).

Paquet et al. discloses a method of controlling growth of *Clostridium botulinum* in manufactured or processed foods employing N-acyl-D-amino acid derivatives which read on instant compound of Formula I. N-acyl methionine is disclosed as the antimicrobial compound therein having anti-microbial activities against organism such as *Clostridium botulinum*. See abstract. The compounds therein having antimicrobial activity are mixed with food additives in the method for control of microorganisms in food products which contain water/moisture, particularly meat-containing products and especially red meat containing products. See abstract; page 2, lines 1-5; page 3, line 19-page 4; claims 18-26. The food products include sausage, canned minced meat products, corned beef, luncheon meats, meat products comminuted and stuffed into casings. See page 4a, lines 15-18; page 6, line 21-page 7, line 10; page 12, Table 2 wherein acetyl-D-methionine is disclosed. Paquet et al. also teach that sorbic acid is known to be used as antimicrobial agent. See page 3, line 5.

Paquet et al. does not specifically teach the combination of N-acyl methionine with other organic acids.

It is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings of Paquet et al., the instant claims contain two antibacterial agents

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acetyl-D-methionine, and organic acid such as sorbic acid. *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

The recitation "wherein said composition has a moisture content of up to about 17 %" in the claim 1 includes 0 % of moisture.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 99-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doerr et al. (Poultry Science, 74 (1), 23, 1995, PTO-892), in view of Rolow et al. (US 6,355,289, PTO-892).

Doerr et al. discloses a method of killing mold in ground corn (19 % moisture) by treating with 0.8 % hydroxy-methylthio butanoic acid. See page 23, abstract.

Doerr et al. does not specifically teach the combination of hydroxy-methylthio butanoic acid with other organic acids.

Rolow teaches a method of extending the shelf life of tortillas made from corn flour by adding mold growth inhibitors such as propionic acid. See abstract; column 1, lines 55-58.

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It is generally considered *prima facie* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Doerr et al. and Rolow et al., the instant claims contain two agents useful for killing mold hydroxy-methylthio butanoic acid, and propionic acid. *In re Kerkhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivey et al. and as evidenced by Blake et al. (US 2,938,053, PTO-892) as applied to claims 75-80, 82-85, 90, 92-93, 96-99, and 104 above, in view of Pinski et al. (US 2002/0172737, PTO-892).

Ivey et al. and Blake et al. are as discussed above.

Ivey et al. do not specifically teach that the formulations therein are mixed with food for feeding animal such as aquaculture.

Pinski et al. teaches a particulate foodstuff which is effective for feeding aquatic life such as crustaceans, fish, shell fish, comprising a particulate nutrient feed and an

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antimicrobial agent which provides shelf life for the foodstuff of at least about 6 months. See page 1, paragraph [0009]. The antimicrobial agent therein is selected from propionic acid, salt of propionic acid, citric acid or salt thereof. See page 5, claim 8.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ the formulation comprising Alimet, propionic acid and citric acid taught by Ivey et al. to mix with feed for aquatic animal because Ivey et al. formulations have antimicrobial properties according to Blake et al, and Pinski teaches that the feed composition for feeding aquatic animals comprise antimicrobial agents.

One of ordinary skill in the art at the time of invention would have been motivated to employ the formulation taught by Ivey et al. in aquatic feed with reasonable expectation of obtaining aquatic feed formulations that have longer shelf life.

Claims 86-87, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivey et al. and as evidenced by Blake et al. (US 2,938,053, PTO-892) as applied to claims 75-80, 82-85, 90, 92-93, 96-99, 104 above, in view of Bland et al. (US 5,591,467, PTO-892).

Ivey et al. and Blake et al. are as discussed above.

Ivey et al. do not specifically teach that the formulations therein are mixed with food for feeding ruminant animal.

Bland et al. teach that the animal feed composition for feeding animals such as poultry, swine, beef, cattle feed, dairy cattle feed, horse, aquaculture and pets comprise antibacterial agents formic acid, propionic acid, lactic acid. It is also taught that mold

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inhibitors, usually containing propionic acid, were added to animal feedstuffs to control mold.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ the formulation comprising Alimet, propionic acid and citric acid taught by Ivey et al. to mix with feed for ruminant animals because Ivey et al. formulations have antimicrobial properties, and Bland teaches that the feed composition for animals such as poultry, swine, beef, cattle feed, dairy cattle feed, horse, aquaculture and pet feed comprise antimicrobial agents.

One of ordinary skill in the art at the time of invention would have been motivated to employ the formulation taught by Ivey et al. in animal feeds because antimicrobial agents are well known to be used in animal feed formulations.

Claims 94-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivey et al. and as evidenced by Blake et al. (US 2,938,053, PTO-892) as applied to claims 75-80, 82-85, 90, 92-93, 96-99, 104 above, in view of Friedman et al. (US 4,495,208, PTO-892).

Ivey et al. and Blake et al. are as discussed above.

Ivey et al. do not specifically teach that the formulations therein are mixed with food for feeding companion animal.

Friedman et al. teach that pet food for feeding pets such as dog food contains antibacterial agents.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ the formulation comprising Alimet, propionic acid and citric acid taught by Ivey et al. to mix with feed for companion animals because Ivey et al. formulations have antimicrobial properties according to Blake et al., and Friedman teaches that the feed composition for companion animals such as cats, and dogs contain antimicrobial agents.

One of ordinary skill in the art at the time of invention would have been motivated to employ the formulation taught by Ivey et al. in dog food because antimicrobial agents are well known to be used in dog food formulations.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Tuesday, Thursday-Friday, 8am-4pm.

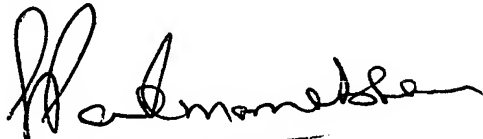
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617



SHEENU PADMANABHAN
SUPERVISORY PATENT EXAMINER